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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,250	09/25/2003	Leland Shapiro	SHAP-000130	3190

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,250	SHAPIRO, LELAND	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 31-33 are presented for examination.

Applicant's Amendment filed March 07, 2007 has been received and entered into present application.

Applicants' arguments, filed March 07, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 31 remains provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/427,929 for the reasons discussed on pages 2-4 of the office action dated January 05, 2006.

Applicant's deferral from commenting until allowable subject matter is indicated has been acknowledged, however the rejection remains.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kolb et al. (Suppression of low dose streptozotocin induced diabetes in mice by administration of a nitric oxide synthase inhibitor), already of record, for the reasons set forth at page 5 of previous office action dated January 05, 2006, of which reasons are herein incorporated by reference.

Claim 31 claims "A method of sparing tissue levels of α_1-antitrypsin in an animal, **comprising administering an effective dose of a nitric oxide synthase inhibitor**. " In claim 32, applicant specifics that the animal is a human, and in claim 33, applicant claims specific nitric oxide synthase inhibitors such as N^G-nitro-L-arginine methyl ester (NAME) and N^G-monomethyl-L-arginine (L-NMMA). Thus all claims are encompassed by a method of administering an effective dose of NAME to a human. As discussed in the previous office action dated January 05, 2006, Kolb et al. teach a method of administering NAME to treat diabetes (abstract). This anticipates claims 31-33 because they are administering a dose of NAME effective to humans with diabetes. The method taught by Kolb et al. would inherently spare tissue levels of α_1-antitrypsin in the humans treated and thus it does not matter if the disease was caused by α_1-antitrypsin levels. The fact that α_1-antitrypsin plays a role in the cause of diabetes merely adds to the inherency argument, in that α_1-antitrypsin is related to diabetes, and thus treatment of diabetics with the method of Kolb et al. would likely treat many of the patients in need of sparing tissue levels of α_1-antitrypsin. However, regardless of the link between α_1-

antitrypsin and diabetes, the method of Kolb et al. would inherently anticipate the method as claimed "comprising administering an effective dose of a nitric oxide synthase inhibitor". Thus claims 31-33 remain rejected over Kolb et al.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Pizcutea et al. (Modulation of hyperdynamic circulation of cirrhotic rates by nitric oxide inhibition), already of record, for the reasons set forth at page 5 of previous office action dated January 05, 2006, of which reasons are herein incorporated by reference.

Claim 31 claims "A method of sparing tissue levels of α_1-antitrypsin in an animal, **comprising administering an effective dose of a nitric oxide synthase inhibitor**. " In claim 32, applicant specifics that the animal is a human, and in claim 33, applicant claims specific nitric oxide synthase inhibitors such as N^G-nitro-L-arginine methyl ester (NAME) and N^G-monomethyl-L-arginine (L-NMMA). As discussed in the previous office action dated January 05, 2006, Pizcutea et al. teach a method of administering L-NMMA to treat cirrhosis and hypertension (abstract). This anticipates claims 31-33 because they are administering a dose of L-NMMA effective to humans with cirrhosis. The method taught by Pizcutea et al. would inherently spare tissue levels of α_1-antitrypsin in the humans treated and thus it does not matter if the disease was caused by α_1-antitrypsin levels. The fact that α_1-antitrypsin plays a role in the cause of diabetes merely adds to the inherency argument, in that α_1-antitrypsin is related to cirrhosis, and thus treatment of cirrhosis with the method of Pizcutea et al. would likely treat many of the patients in need of sparing tissue levels of α_1-antitrypsin. However, regardless of

the link between α_1-antitrypsin and cirrhosis, the method of Pizcutea et al. would inherently anticipate the method as claimed "comprising administering an effective dose of a nitric oxide synthase inhibitor". Thus claims 31-33 remain rejected over Pizcutea et al.

In response to applicant's arguments that the claims must meet "each and every element as set forth in the claim" (page 3), the prior art references of Kolb and Pizcutea et al. do each, independently meet those limitations, because what is being claimed is a method "comprising administering an effect dose of a nitric oxide synthase inhibitor" and thus they do meet all the limitations of the claim. The cause of the disease being treated does not matter, and the rejections are not improper due to the fact that the specific animals tested in Kolb and Pizcutea et al. were given diseases due to chemical exposure. The claims do not claim methods of treatment of animals which suffer from decreases in α_1-antitrypsin levels. Any animal or human is claimed, and thus the methods above anticipate the method as claimed.

As discussed above, in the rejection of claims 31-33, the method of administering a NOS inhibitor is anticipated by Kolb and Pizcutea et al. Applicant's argument is not deemed persuasive and thus the rejection of claims 31-33 is **maintained.**

Conclusion

Rejection of claims 31-33 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614